5. 510(K) SUMMARY

JUL 28 2011

SUBMITTED BY:

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DATE PREPARED: April 21, 2011

NAME OF DEVICE: MRI-Q System

CLASSIFICATION NAME: Picture Archiving and Communication System (PACS)
(21 CFR 892.2050)

CLASSIFICATION NUMBER: 90 LLZ

TRADE/PROPRIETARY NAME: MRI-Q System

PREDICATE DEVICE(S):	K043271:	Resonance Health Analysis Services R_2-MRI Analysis System
	K073194	Cardiovascular Imaging Solutions Ltd. CMRtools and plug-in ThalassaemiaTools
DEVICE DESCRIPTION:		Stand alone software package used to facilitate the import, visualization and analysis of multi-slice gradient echo MRI data sets encompassing cardiac tissue, to quantify the signal decay rate (R_2*) and time (T_2*).
SCIENTIFIC CONCEPTS:		The operational principle of the MRI-Q System is based on fitting signal decay curves to magnetic resonance image signal intensities acquired at different echo times on a voxel-by-voxel (3-D pixel) basis to determine the signal decay rate (R_2*) and time (T_2*).
INTENDED USE:		The MRI-Q System is intended to provide additional processing of images for the analysis of multi-slice gradient echo MRI data sets of cardiac tissue to quantify the signal decay rate (R_2*) and time (T_2*).

SUBSTANTIAL EQUIVALENCE INFORMATION:

The device has been shown to be substantially equivalent to the Resonance Health Analysis Services R_2-MRI Analysis System (K043271) and the Cardiovascular Imaging Solutions Ltd CMRtools and plug-in ThalassaemiaTools (K073194).

CONCLUSION:

The 510(k) premarket notification for the MRI-Q System contains adequate information and data to enable the FDA-CDRH to determine substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Resonance Health Analysis Services PTY, Ltd.
% Mr. Greg Holland
Regulatory Specialist
Regulatory Specialists, Inc.
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JUL 28 2011

Re: K111222
Trade/Device Name: MRI-Q System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 27, 2011
Received: May 2, 2011

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111222

Device Name: MRI-Q System

Indications For Use: The MRI-Q System is a software device that provides quantitative analysis of magnetic resonance image signal decay parameters in cardiac tissue. The device contains an image viewer for importing DICOM images, browsing through datasets and performing quantitative region of interest analysis. The software device has capability to measure the signal decay rate (R_2*) and time (T_2*) in heart tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation & Safety (OIVD).

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111222